

A new Era in Oncology



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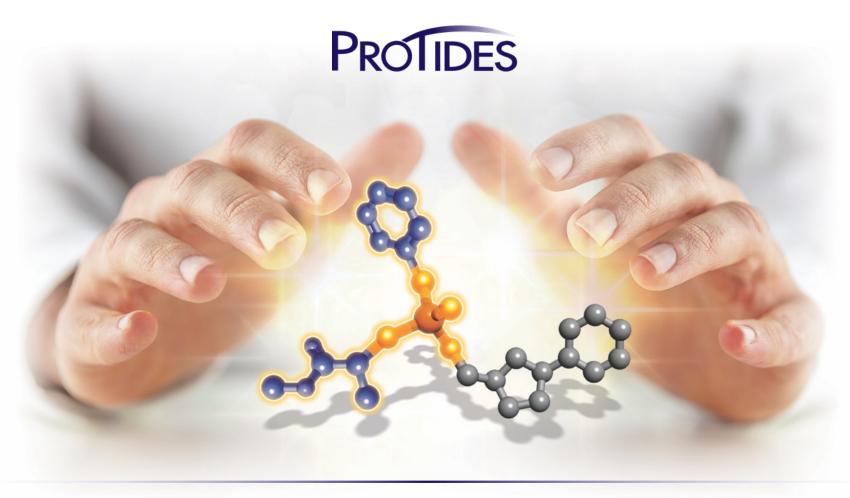
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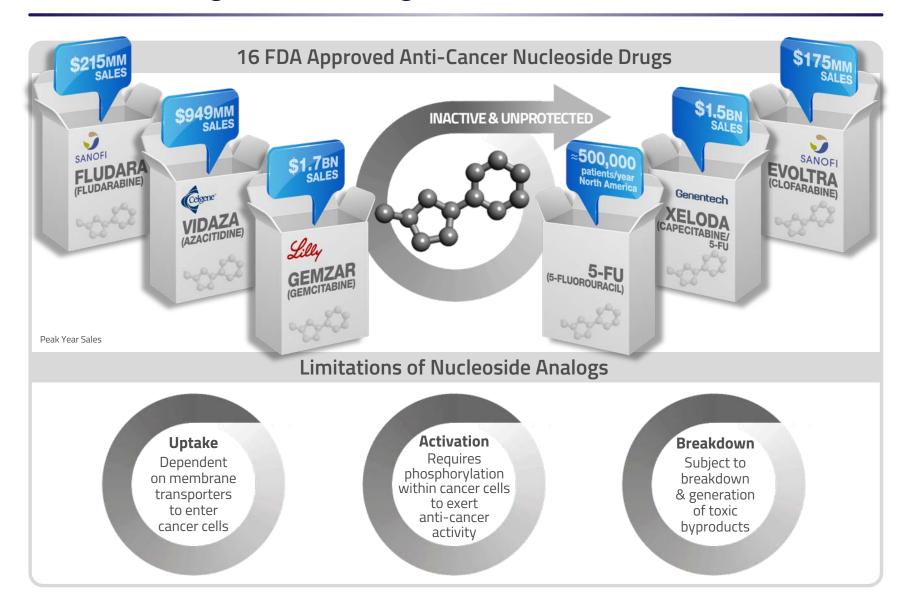
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## Harnessing the Power of Phosphoramidate Chemistry

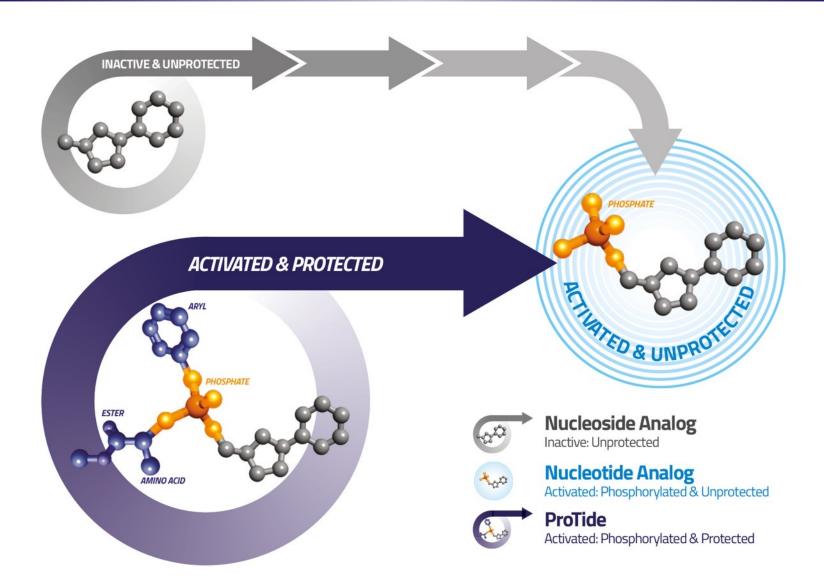


A New Era in Oncology

#### **Nucleoside Analogs: Flawed ProDrugs**



#### **Transforming Nucleoside Analogs into ProTides**



#### **ProTides: A New Era In Anti-Virals**

















Veklury® remdesivir



#### **Transforms Therapeutic Index**

#### **Overcomes Viral Resistance Mechanisms**

<sup>\*</sup> Sovaldi + Harvoni + Epclusa + Vosevi cumulative sales through 31 December 2020

<sup>\*\*</sup> Genvoya + Descovy + Odefsey + Biktarvy + Symtuza cumulative sales through 31 December 2020

#### **ProTides: A New Era in Oncology**















#### **Transforms Therapeutic Index**

#### **Overcomes Cancer Resistance Mechanisms**

<sup>&</sup>lt;sup>1</sup> Efficacy evaluable patients with advanced biliary tract cancers (n=16) - McNamara et al (2020) The Oncologist;25: 1-10

<sup>&</sup>lt;sup>2</sup> Pre-clinical data - Ghazaly et al ESMO September 2017

<sup>&</sup>lt;sup>3</sup> Pre-clinical data – Symeonides et al ESMO September 2020

## **Development Status: Current**

	ACELARIN	PRE-CLINICAL	PHASE I	PHASE II	PHASE III
	Biliary				
4	NUC-3373				
	Solid Tumors				
	Colorectal				
4	NUC-7738				
	Solid Tumors				
	Hematologic				

## **Development Status: Planned End 2021**

-ACELAPIN	PRE-CLINICAL	PHASE I	PHASE II	PHASE III
Biliary				
NUC-3373				
Solid Tumors				
Colorectal				
NUC-7738				
Solid Tumors				
Hematologic				

#### **Strong Balance Sheet & Multiple Inflection Points**





Cash & Cash Equivalents at December 31, 2020 ~\$119 million\* **Important Data Readouts** 

throughout **2021 & 2022** 

\*Based on exchange rate of £1.00 to \$1.36 at 31 December 2020

#### Well Capitalized to Achieve Key Milestones



- Complete ongoing Phase III BTC study (NuTide:121)
- File NDA for BTC

NUC-3373

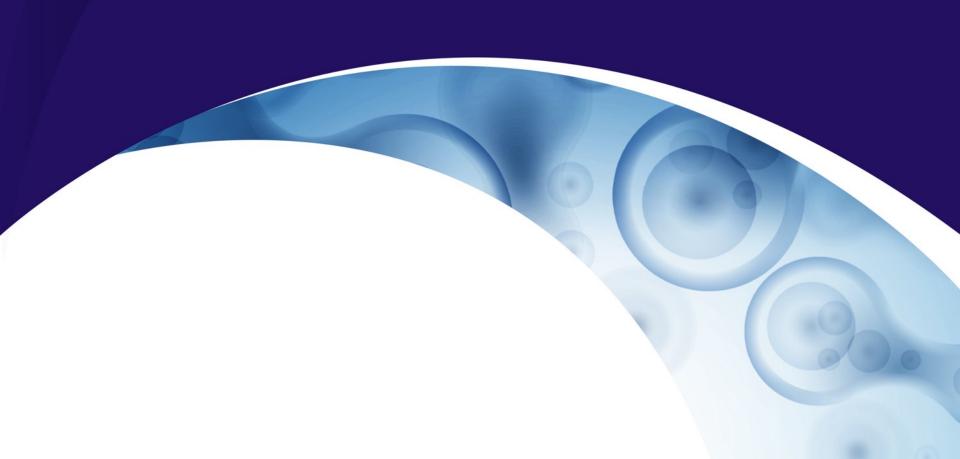
- Complete ongoing Phase I solid tumor study (NuTide:301)
- Complete ongoing Phase Ib CRC study (NuTide:302)
- Complete Phase Ib expansion / Phase II CRC study
- Initiate and complete Phase III CRC study
- File NDA for CRC

NUC-7738

- Complete ongoing Phase I study (NuTide:701)
- Initiate and complete Phase II study



A transformation of gemcitabine



#### **CELAPIN**: Overview of Gemcitabine



- · WHO list of essential medicines
- First approved for medical use in 1995
- · Approved in pancreatic, ovarian, breast & lung
- Widely used in other cancers
- Peak annual sales of \$1.7 billion





#### **Limitations of Gemcitabine**



**Uptake**Dependent on membrane transporters to enter cancer cells

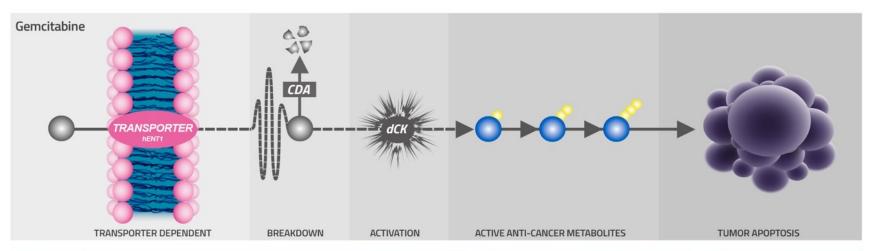


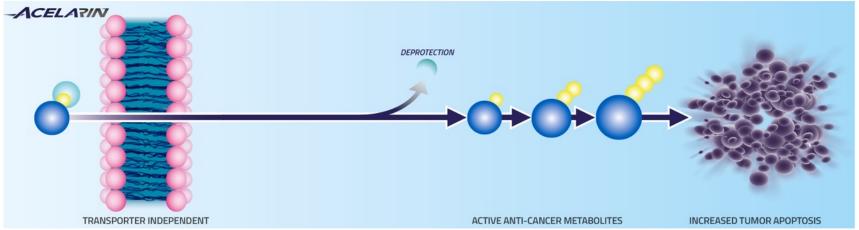
**Breakdown**Subject to breakdown and generation of toxic
byproducts



Activation
Requires phosphorylation within cancer cells to exert anti-cancer activity

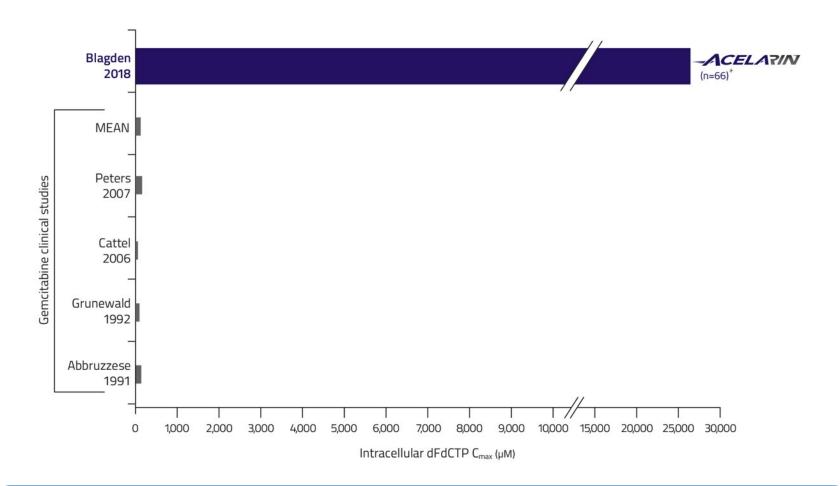
## **CELAPIN**: Overcomes The Key Cancer Resistance Mechanisms







#### **CELAPIN**: Very High Intracellular dFdCTP (Cmax)

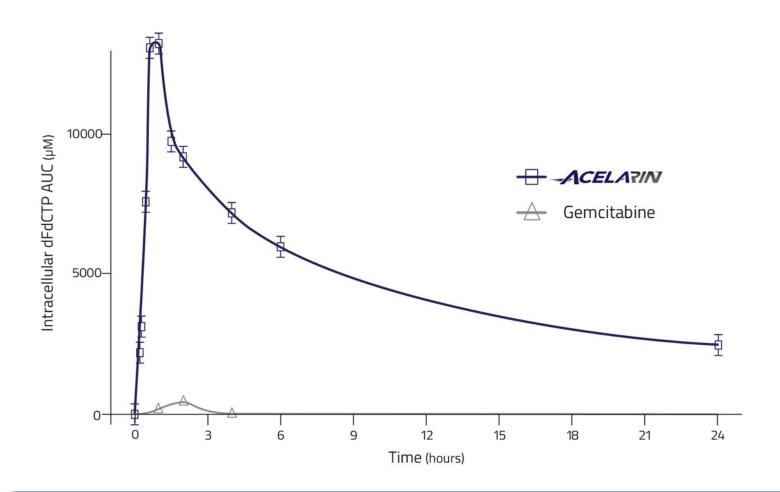


CELATIN achieved 217x higher intracellular levels of dFdCTP than gemcitabine

Equimolar dose comparison

<sup>\*</sup> Blagden et al (2018) Br J Cancer; 119:815-822

#### CELATIN: Very High Intracellular dFdCTP (AUC)



**CELATIN** achieved **139x** greater intracellular AUC of dFdCTP than gemcitabine

Blagden *et al* (2015) *J Clin Oncol*; 33; Suppl Abstract ID: 2547 (ASCO poster May 2015) Cattel *et al* (2006) *Annals Onc* (supp); 17: v142-v147 Blagden *et al* (2018) *Br J Cancer*; 119:815-822

#### CELAPINV: Phase 1 Study (monotherapy)



- Phase 1 dose-escalation study in patients with advanced solid tumors
- All patients had metastatic spread
- Rapidly progressing disease
- Exhausted all other therapeutic options
- Objective: Recommended Phase 2 dose

PRO-001

Number of patients

68

Evaluable patients (≥2 cycles)

49

Primary cancer types

19

Age (median)

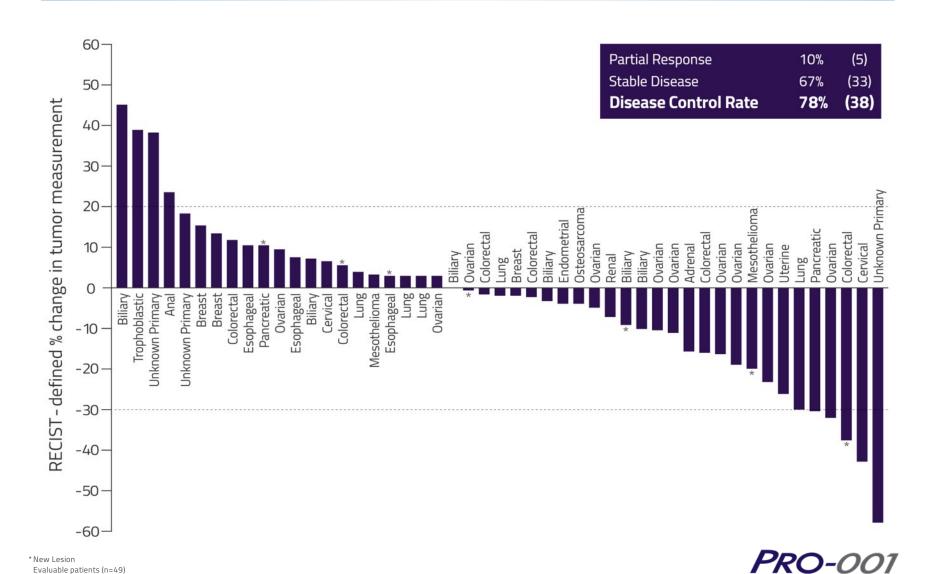
**56** (range 20-83)

Prior chemotherapy regimens

(range 1-10)

Blagden et al (2018) Br J Cancer; 119:815-822

## CELATIN: PRO-001 Study Best Overall Response (monotherapy)



NUCANA

Blagden et al (2018) Br J Cancer; 119:815-822

#### CELATIN: Ovarian Phase 1b Study (combination)



- Combination: Acelarin + carboplatin
- Dose escalation: 3 + 3
  - Acelarin: 500 mg/m<sup>2</sup> to 750 mg/m<sup>2</sup>
  - Carboplatin: AUC 4 to 5
- All patients had metastatic spread
- Rapidly progressing disease
- Objective: Recommended Phase 2 dose

PRO-002

Number of patients

25

Evaluable patients (≥1 cycle)

23

Age (median)

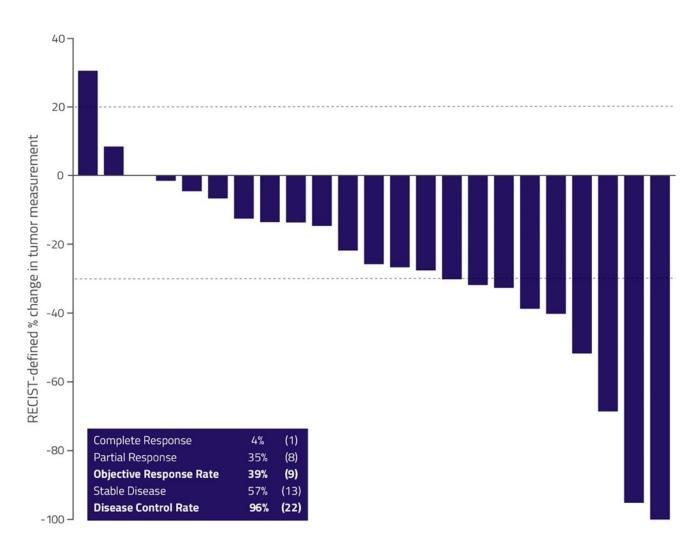
**64** (range 37-77)

Prior chemotherapy regimens

(range 2-8)

Blagden et al (2017) Ann Oncol; 28; Suppl 5 Abstract ID: 968P (ESMO poster September 2017)

### CELATIN: PRO-002 Study Best Overall Response (combination)



Evaluable patients (n=23)
Blagden *et al* (2017) *Ann Oncol*; 28; Suppl 5 Abstract ID: 968P (ESMO poster September 2017)
Data as of September 2017

PRO-002

#### CELATIN: Biliary Phase 1b Study (combination)



- First-line treatment
- Locally advanced or metastatic biliary tract cancer
- Objectives: Safety & Dose Selection
  - Cohort 1: Acelarin 625mg/m<sup>2</sup> + cisplatin 25mg/m<sup>2</sup> (n=8)
  - Cohort 2: Acelarin 725mg/m<sup>2</sup> + cisplatin 25mg/m<sup>2</sup> (n=6)
  - Cohort 3: Acelarin 625mg/m<sup>2</sup> + cisplatin 25mg/m<sup>2</sup> (n=7)

ABC-08

Number of patients

21

Evaluable patients\*

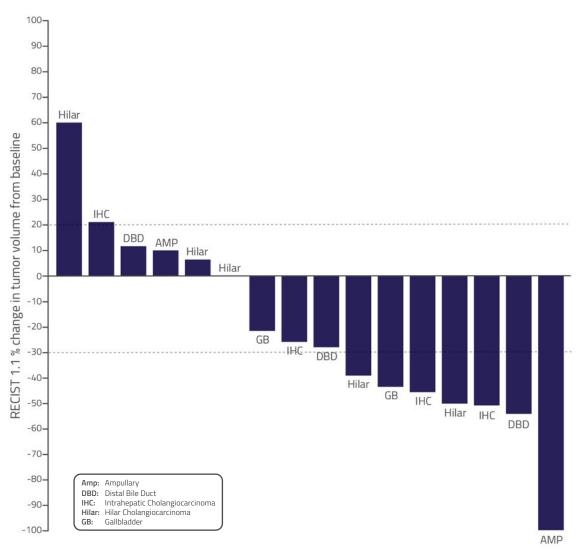
16

Age (median)

**61** (range 47-78)

<sup>\*</sup> Efficacy evaluable patients: measurable disease at baseline; ≥1 cycle Acelarin; ≥1 follow-up radiographic assessment McNamara et al (2020) Oncologist; 26 (4):e699-e678

## CELATIN: ABC-08 Best Overall Response



McNamara *et al* (2020) *Oncologist*; 26 (4):e699-e678 Efficacy Evaluable Population

ABC-08

#### CELATIN: ABC-08 and ABC-02 Comparison

ABC-08 Study

(625 & 725 mg/m²) + cisplatin

**Complete Response** 

6% (1/16)

**Partial Response** 

38% (6/16)

**Objective Response Rate** 

44% (7/16)

ABC-02 Study

Gemcitabine

(1000 mg/m<sup>2</sup>) + cisplatin

**Complete Response** 

0.6% (1/161)

**Partial Response** 

25% (41/161)

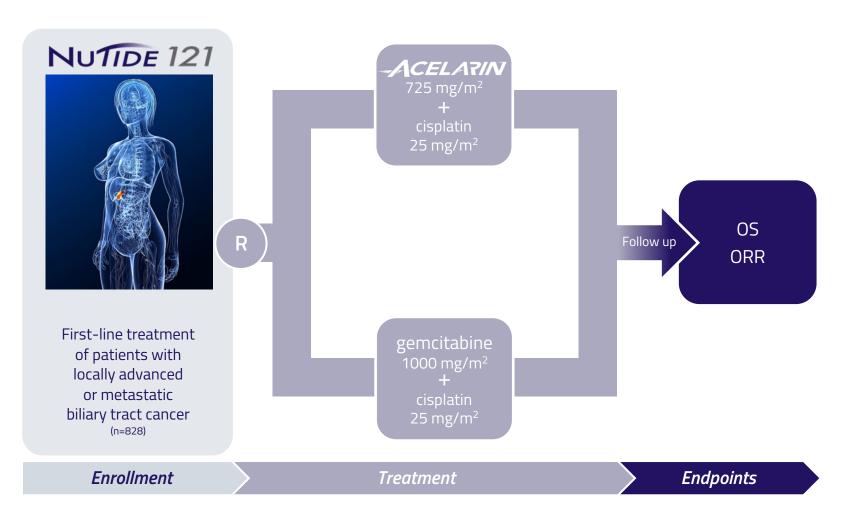
**Objective Response Rate** 

26% (42/161)

McNamara *et al* (2020) *Oncologist*; 26 (4):e699-e678 Valle *et al* (2010). *N Eng J Med*; 362: 1273-1281 Efficacy Evaluable Population

ABC-08

## **CELAPIN**: Ongoing Biliary Phase 3 Study





#### CELAPIN: Biliary Phase 3 Study (Statistical Plan)

Primary Endpoints: OS; ORR

RECRUITMENT	FOLL	OW UP	FINAL ANALYSIS		
	d Approval signed to support				
		Regular Approval Interim 2, 3 or 4 designed to support			
Interim1	Interim 2	Interim 3	Final		
ORR 418 evaluable patients DIP≥14% <sup>#</sup>	<b>ORR</b> 644 evaluable patients DIP≥9% <sup>#</sup>				
	<b>OS</b> ~425 events DIM ≥3.4m*	<b>OS</b> ~541 events DIM ≥2.6m*	<b>Final OS</b> ~637 events DIM ≥2.2m*		



<sup>#</sup> DIP = Difference in observed proportions (vs. an estimated 19.0%) for statistical significance. Measurable disease at baseline and ≥28 weeks follow-up.

<sup>\*</sup> DIM = Difference in observed medians (vs. an estimated 11.7 months) for statistical significance.

# NUC-3373

A transformation of 5-FU

#### **NUC-3373**: Overview of Fluorouracil (5-FU)



- WHO list of essential medicines
- First approved for medical use in 1962
- ~500,000 patients receive 5-FU annually in North America
- Unpredictable PK profile
- 10-15% Overall Response Rate (colorectal cancer)





#### **Limitations of Fluorouracil** (5-FU)



**Breakdown**>85% breakdown by DPD,
generating toxic
byproducts



**Transport**Requires
active
transport

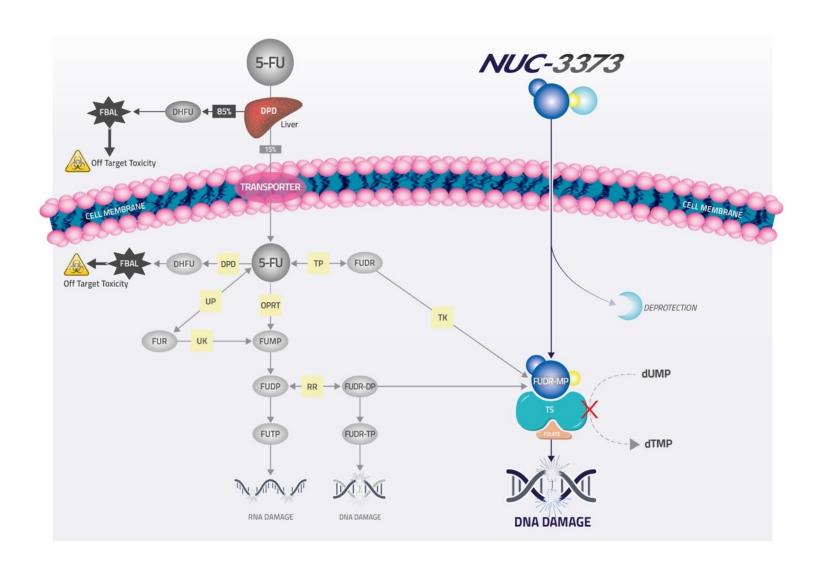


**Activation**Multi-step
phosphorylation
process

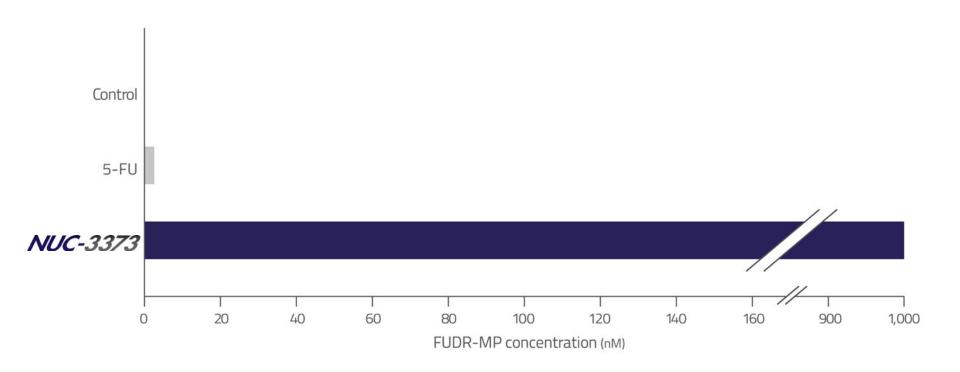


**Dosing** 46-hour continuous infusion

## **NUC-3373**: 5-FU Metabolism and Mechanism of Action Comparison



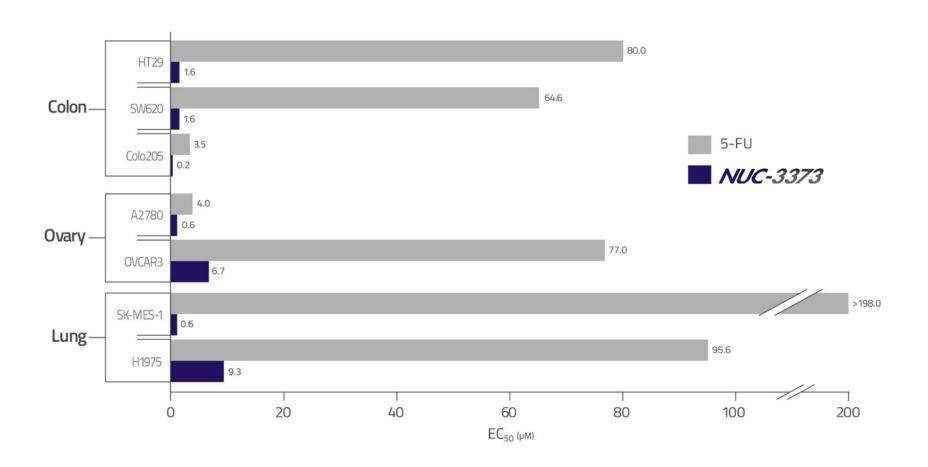
## **NUC-3373**: Very high Intracellular FUDR-MP (pre-clinical)



**NUC-3373** generated **366x** higher levels of active anti-cancer metabolite FUDR-MP than 5-FU

Equimolar dose comparison Ghazaly *et al* (2017) *Ann Oncol*; 25: Suppl 5 Abstract ID:385P (ESMO poster September 2017)

## **NUC-3373**: Greater Anti-Cancer Activity than 5-FU (pre-clinical)



**NUC-3373** had up to **330x** greater anti-cancer activity than 5-FU

Ghazaly et al (2017) Ann Oncol; 25: Suppl 5 Abstract ID:385P (ESMO poster September 2017)

## **NUC-3373**: Ongoing Phase 1 Study



- Phase 1 dose-escalation study in patients with advanced solid tumors
- All patients have metastatic spread
- Rapidly progressing disease
- Exhausted all other therapeutic options
- Objective: Recommended Phase 2 dose + schedule



Number of patients (enrolled to date)

36

Age (median)

**60** (range 21-78)

Prior chemotherapy regimens

(range 1-6)

Blagden *et al* (2018) *Ann Oncol*; 29: Suppl 8 Abstract ID: 442TiP (ESMO poster October 2018) Data as of September 2018

#### **NUC-3373**: Ongoing Solid Tumor Phase 1 Study (interim data)

#### Favorable safety profile

- NUC-3373 is well-tolerated
- No hand-foot syndrome

- Grade 3 treatment-related AEs (3 transaminitis, 1 fatigue, 1 shingles)
- No Grade 4 AEs

#### Metastatic Colorectal Cancer

#### 70 years, male **6 prior lines**

1) 5-FU:

based chemoradiotherapy (adjuvant)

2) FOLFIRI:

for metastatic disease

3) CAPOX:

progressed within 2 months

4) FOLFIRI:

progressed within 8 months

5) LONSURF:

progressed within 3 months

6) Irinotecan:

treatment for 1 month

NUC-3373 1,500 mg/m<sup>2</sup> q1w

Stable Disease: 9 months

#### Metastatic Basal Cell Carcinoma

## 55 years, male **2 prior lines**

1) Vismodegib:

for 11 months

2) Paclitaxel + carboplatin: for **3 months** 

NUC-3373 1,500 mg/m<sup>2</sup> q2w

Stable Disease: 10 months

#### Metastatic Cholangiocarcinoma

#### 60 years, female 1 prior line

1) Gemcitabine + cisplatin: progressed within **6 months** 

NUC-3373 1,125 mg/m<sup>2</sup> q1w

Stable Disease: 11 months



Blagden et al (2018) Ann Oncol; 29: Suppl 8 Abstract ID: 442TiP (ESMO poster October 2018) Data as of September 2018

## **NUC-3373**: Ongoing Colorectal Phase 1b Study



- Patients with advanced colorectal cancer
- Rapidly progressing disease
- Received ≥2 prior lines of fluoropyrimidine-based regimens
- Exhausted all other therapeutic options
- Objective: Dose + Schedule in combination with other agents



Number of patients (enrolled to date)

38

Age (median)

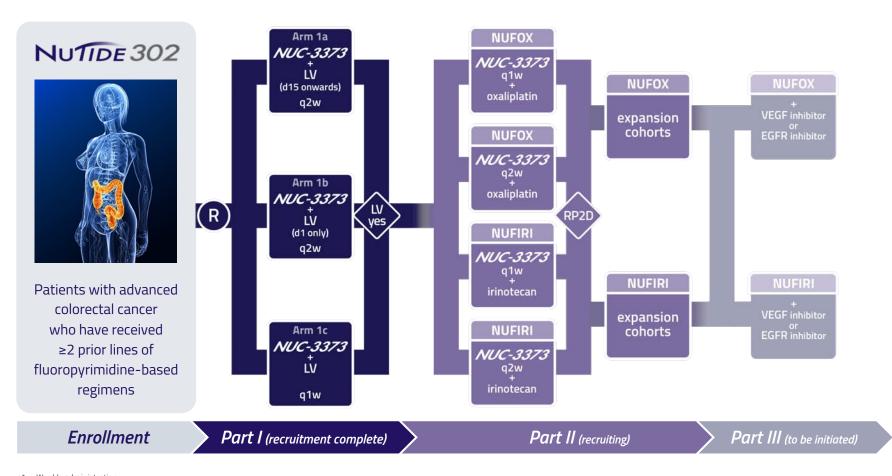
**58** (range 33-75)

Prior chemotherapy regimens

(range 2-13)

Kazmi et al (2021) Abstract ID: CT140 (AACR April 2021)

## **NUC-3373**: Ongoing Colorectal Phase 1b Study



q1w: Weekly administration q2w: Alternate weekly administration

VEGF (e.g. bevacizumab) EGFR (e.g. cetuximab)

NUTIDE 302

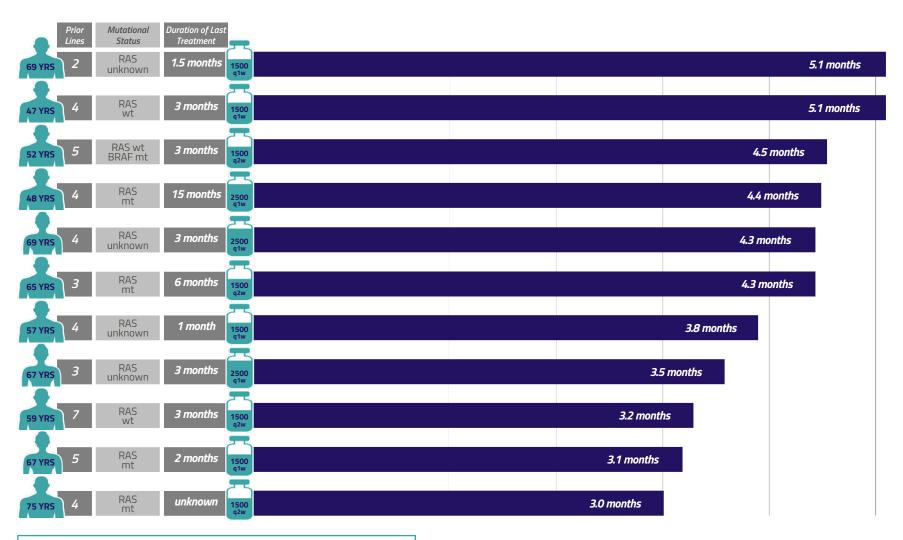
## **NUC-3373**: Favorable Safety Profile

	NUC-3373 (n=38)		5-FU IV (n=143)		5-FU Bolus (n=593)		Capecitabine (n=596)	
	All Grades (%)	G3 or G4 (%)	All Grades (%)	G3 or G4 (%)	All Grades (%)	G3 or G4 (%)	All Grades (%)	G3 or G4 (%)
Diarrhea	32	0	45	6	61	12	55	15
Nausea	42	5	55	4	51	4	43	4
Vomiting	34	0	32	3	30	5	27	5
Mucositis/Stomatitis	8	0	29	3	62	15	25	3
Hand-foot syndrome	0	0	13	1	6	1	54	17
Dermatitis	11	0	20	0	26	1	27	1
Fatigue/lethargy	34	3	NR	NR	46	4	42	4
Anemia	8	3	91	2	79	2	80	3
Neutropenia	0	0	48	13	46	21	13	3
Elevated bilirubin	8	5	36	11	17	6	48	23
	Heavily pre-treated patients NUC-3373/LV q1w or q2w		First-line patients 5-FU/LV infusional days 1&2, q2w		First-line patients 5-FU/LV bolus days 1-5, q4w		First-line patients Capecitabine BID, 2wks on, 1wk off	

- Grade 4 treatment-related AE (1x bilirubin)
- Grade 3 treatment-related AEs (2x ALT, 2x ALP, 2x nausea, 1x bilirubin, 1x AST, 1x anemia, 1x hyponatremia, 1x fever, 1x fatigue)
- FUTP, the primary cause of 5-FU toxicity and a dose-limiting factor, has not been detected in NUC-3373 treated patients



#### **NUC-3373**: Colorectal Cancer Patient Case Studies



**Disease Control Rate: 62%** (efficacy evaluable population n=26)

Kazmi et al (2021) Abstract ID: CT140 (AACR April 2021)



### **NUC-3373**: Ongoing Colorectal Phase 1b Study (interim data)

#### **Colorectal Cancer**

## 67 years, female 3 prior lines

1) CAPOX (adjuvant):
for **3 months**relapsed 9 months post-adjuvant therapy

2) FOLFIRI: progressed within **3 months** 

3) Lonsurf: progressed within **3 months** 

RAS unknown
Target lesions: 1 (peritoneum)

NUC-3373 2,500 mg/m<sup>2</sup> q1w

40% reduction in tumor volume

Partial Response: 3.5 months

#### **Colorectal Cancer**

## 69 years, male **2 prior lines**

Diagnosed with metastatic disease

1) CAPOX:

progressed within 2 months tumor increase of 35%

2) FOLFIRI:

progressed within 1.5 months

RAS unknown Target lesions: 2 (liver)

NUC-3373 1,500 mg/m<sup>2</sup> q1w

28% reduction in tumor volume

Stable Disease: **5.1 months**\*

#### **Colorectal Cancer**

## 52 years, male **5 prior lines**

1) FOLFOX (adjuvant):

for 4 months

relapsed 4 months post-adjuvant therapy

2) FOLFIRI:

progressed within 6 months

3) Irinotecan + panitumumab: progressed within **6 months** 

4) Irinotecan + panitumumab + telaglenastat: progressed within **6 months** 

5) Nivolumab + enadenotucirev: progressed within **3 months** 

RAS wildtype; BRAF mutant Target lesions: 3 (2 lung; 1 liver)

> NUC-3373 1,500 mg/m<sup>2</sup> q2w

15% reduction in tumor volume

Stable Disease: 4.5 months



Graham et al (2020) Ann Oncol 31: Suppl 4 Abstract ID: 464P (ESMO poster September 2020)
Coveler et al (2021) J Clin Oncol 39: Suppl 3 Abstract ID: 93 (ASCO GI poster January 2021)



<sup>\*</sup> patient missed 6 consecutive doses due to COVID-19 and progressed, but continued on study for a total of 8 months due to clinical benefit

### **NUC-3373**: Ongoing Colorectal Phase 1b Study (interim data)

#### **Colorectal Cancer**

#### 47 years, male 4 prior lines

- FOLFOX (adjuvant):
   for **5 months** relapsed 8 months post-adjuvant therapy
- 2) FOLFIRI: + bevacizumab progressed within 18 months
- 3) FOLFIRI + cetuximab: progressed within **8 months**
- 4) Lonsurf: toxicity within **3 months**

RAS wildtype
Target lesions: 5 (2 lymph nodes;
2 peritoneum; 1 liver)

NUC-3373 1,500 mg/m<sup>2</sup> q1w

Stable Disease: 5.1 months

#### **Colorectal Cancer**

#### 57 years, male 4 prior lines

- 1) CAPOX (neoadjuvant/adjuvant):
  for **6 months**relapsed 2 months post-adjuvant therapy
- 2) FOLFIRI: progressed within **3 months**
- 3) Lonsurf: progressed within **2 months**
- 4) RXC004 (Wnt inhibitor): progressed within **1 month**

RAS unknown
Target lesions: 3 (lung)

NUC-3373 1,500 mg/m<sup>2</sup> q1w

Stable Disease: 3.8 months

#### **Colorectal Cancer**

## 67 years, female **5 prior lines**

- 1) FOLFOX (adjuvant):
  for **5 months**relapsed 2 years post-adjuvant therapy
- 2) FOLFIRI: for **5 months**
- 3) Irinotecan + Lonsurf + bevacizumab for **33 months**
- 4) CAPOX: progressed within **1 month**
- 5) Regorafenib: progressed within 2 months

RAS mutant Target lesions: 2 (1 liver; 1 abdomen)

> NUC-3373 1,500 mg/m<sup>2</sup> q1w

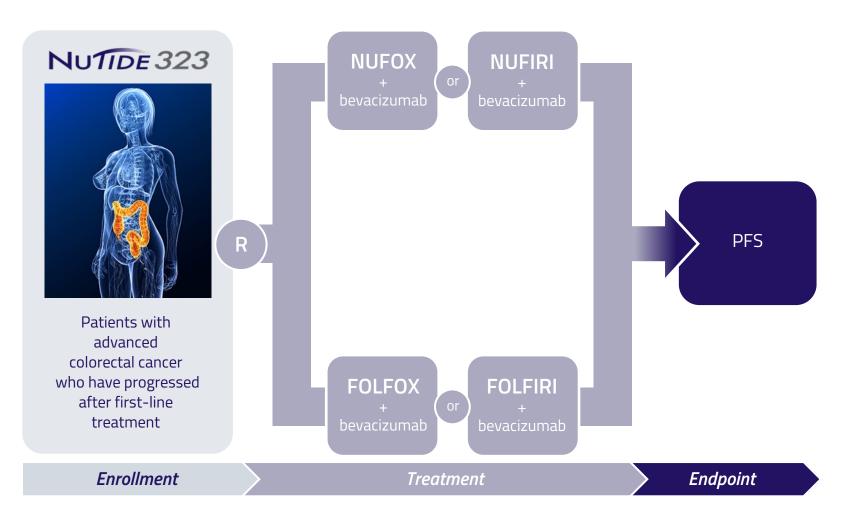
Stable Disease: 3.1 months



Graham et al (2020) Ann Oncol 31: Suppl 4 Abstract ID: 464P (ESMO poster September 2020)
Coveler et al (2021) J Clin Oncol 39: Suppl 3 Abstract ID: 93 (ASCO GI poster January 2021)



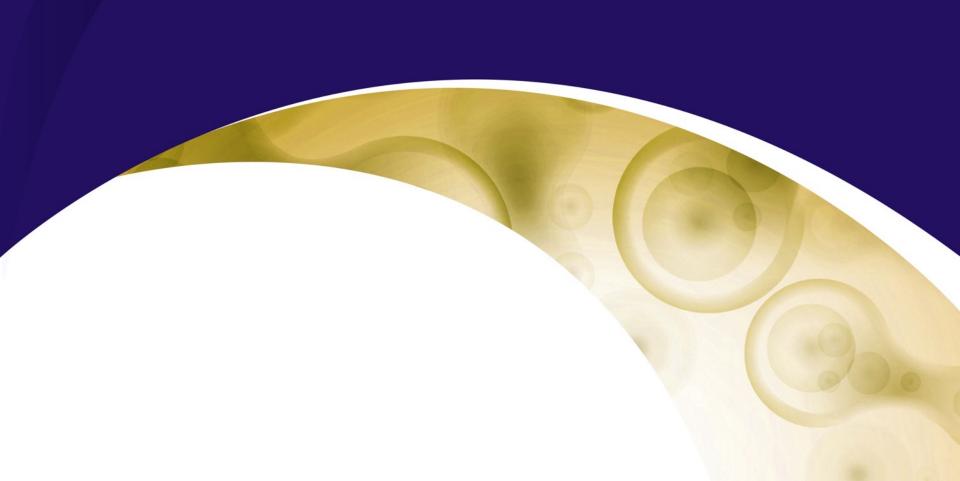
## **NUC-3373**: Potential Colorectal Phase 3 Study





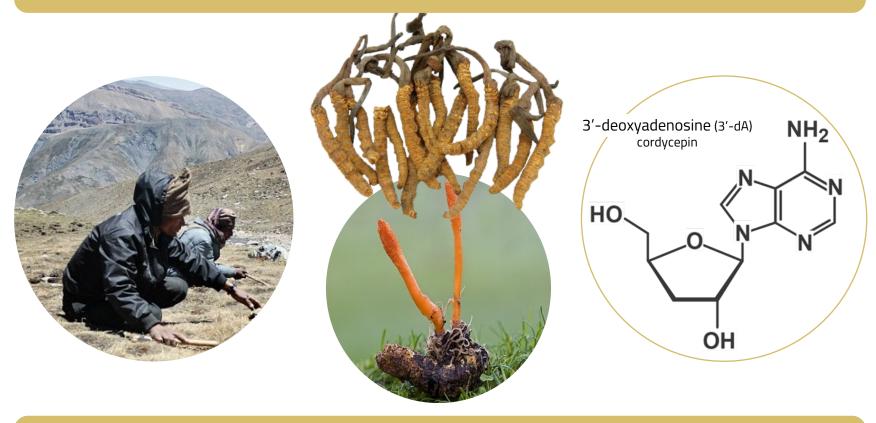
## NUC-7738

A transformation of 3'-deoxyadenosine



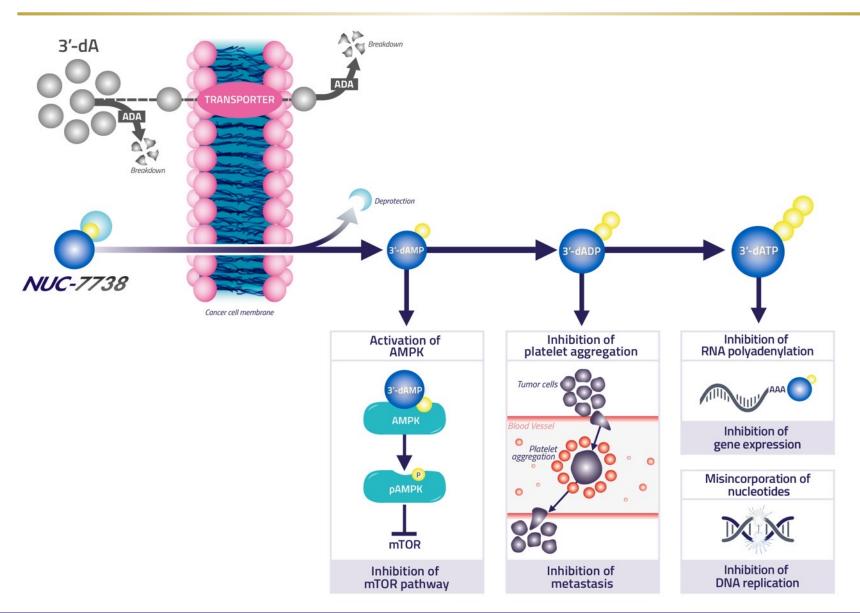
## **NUC-7738**: Origin of 3'-deoxyadenosine

### Cordycepin: A Traditional Chinese Medicine



1950: **3'-dA** isolated from *Cordyceps sinensis* 

## **NUC-7738**: Multiple Anti-Cancer Modes of Action



## **NUC-7738**: Ongoing Phase 1 Study



- Phase 1 dose-escalation study in patients with advanced solid tumors
- All patients have metastatic spread
- Rapidly progressing disease
- Exhausted all other therapeutic options
- Objective: Recommended Phase 2 Dose + Schedule



Number of patients (enrolled to date)

21

Age (median)

**63** (range 46-76)

Prior chemotherapy regimens

(range 1-5)

Plummer et al (2021) Abstract ID: CT136 (AACR April 2021)

### **NUC-7738**: Ongoing Solid Tumor Phase 1 Study (interim data)

#### Favorable safety profile

- No Grade 3 or 4 treatment-related AEs
- No DLTs

#### Attractive PK profile

- Efficient conversion of NUC-7738 to 3'-dATP
- Prolonged intracellular half-life of 3'-dATP (>50 hours)

#### Metastatic Melanoma

## 62 years, female **2 prior lines**

- 1) Nivolumab + ipilimumab: discontinued within **1 month**
- 2) CK7 inhibitor: progressed within **1 month**

Target lesion: 1 (pelvic side wall)

#### NUC-7738

Starting dose 14 mg/m<sup>2</sup> q1w (8 dose escalations)

14% reduction in tumor volume

## Treatment Duration: 18 months

(Stable disease for 12 months, then re-established)

#### Metastatic Melanoma

## 65 years, female 1 prior line

1) Nivolumab + ipilimumab: discontinued within **1 month** 

Target lesion: 1 (lung)

#### NUC-7738

Starting dose 400 mg/m<sup>2</sup> q1w (1 dose escalation)

**7% reduction** in tumor volume

## Treatment Duration: 9 months (ongoing)

(Stable disease for 8 months, then re-established)

#### Metastatic Lung Adenocarcinoma

## 65 years, male **2 prior lines**

- 1) Carboplatin + pemetrexed: progressed at **6 months**
- 2) Docetaxel: progressed at **4 months**

Target lesions: 2 (lung)

#### NUC-7738

Starting dose 42 mg/m<sup>2</sup> q1w (4 dose escalations)

46% reduction in target lesion 1

Treatment Duration: 6 months



Plummer et al (2021) Abstract ID: CT136 (AACR April 2021)

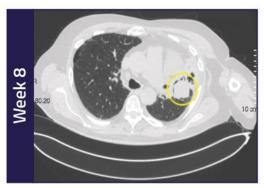
### **NUC-7738**: Ongoing Solid Tumor Phase 1 Study (interim data)

#### Metastatic Lung Adenocarcinoma

#### 65 years, male - 2 prior lines

#### **Target Lesion 1:**

Encouraging signs of anti-tumor activity with a **46% reduction** in lesion between week 8 -16 (41mm to 22mm)

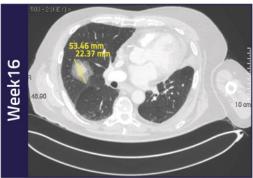




#### **Target Lesion 2:**

Positive change in character (week 8 -16), with a smaller dense core surrounded by a larger diffuse "ground-glass" periphery







Symeonides et al (2020) Ann Oncol: 31: S501 Abstract ID: 600TiP (ESMO poster September 2020)

### **Strong Intellectual Property Position**

Worldwide exclusive rights for all programs: **659 granted patents** and **371 pending applications**\*

Key Patents	Status	Expiration <sup>+</sup> (excluding any extensions)	Territories		
-ACELATIN	432 granted, 185 pending, including:				
Composition of matter	Granted (EP, US); Pending (JP)	2033 / 2035	+ others		
Formulation	Granted (EP, US); Pending (JP)	2035	+ others		
Manufacturing process	Granted (US), Pending (EP, JP)	2035 / 2036	+ others		
Use	Granted (EP, US); Pending (JP)	2035 / 2038	+ others		
NUC-3373	61 granted, 105 pending, including:				
Composition of matter	Granted (US, EP, JP)	2032	+ others		
Formulation	Pending	2036	+ others		
Manufacturing process	Pending	2038	+ others		
Use	Pending	2037 / 2038	+ others		
NUC-7738	52 granted, 31 pending, including:				
Composition of matter	Granted (EP, US, JP)	2035	+ others		
Formulation	Pending	2036	+ others		
Manufacturing process	Pending	2038	+ others		
Use	Pending	2042	+ others		

<sup>\*</sup>Expiration for pending patents if granted

<sup>\*</sup>As of 9 March 2021

## **Key Milestones: 2021**

ACELATIN	PHASE	EVENT	2021 1H 2H	
Biliary	Phase III	Complete recruitment for first interim analysis		Х
NUC-3373				
Solid Tumors	Phase I	Data	X	
Colorectal	Phase Ib	Data	Х	
Colorectal	Phase Ib expansion / Phase II	Data	Х	Х
Colorectal	Phase III	Initiate study		Х
NUC-7738				
Solid Tumors / Hematologic	Phase I	Data	Х	
Solid Tumors / Hematologic	Phase II	Initiate study		X

### **Investment Highlights**

### Improving Survival Outcomes

Focused on significantly improving survival outcomes for patients with cancer by applying our phosphoramidate chemistry technology

#### **Broad IP Protection**

Strong IP position for all product candidates and worldwide exclusive rights

### **Significant Milestones**

Numerous value inflection points throughout 2021 and 2022

#### First-In-Class

Acelarin has achieved impressive response rates and has the opportunity for accelerated approval in front-line biliary tract cancer

#### Standard of Care

NUC-3373 has the potential to replace 5-FU in colorectal cancer and other solid tumors

#### **Novel ProTide**

NUC-7738 is a transformation of a novel nucleoside analog and has multiple anti-cancer modes of action

### **Experienced Team**

Nasdaq : NCNA

Accomplished management team, backed by leading biotech investors



# NUCANA

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